LETTERS PATENT

Number **514481**

ELIZABETH THE SECOND, by the Grace of God Queen of New Zealand and Her Other Realms and Territories, Head of the Commonwealth, Defender of the Faith; To all to whom these presents shall come, Greeting:

WHEREAS pursuant to the Patents Act 1953 an application has been made for a patent of an invention for

Vacuum assisted closure system with provision for introduction of agent

(more particularly described in the complete specification relating to the application)

AND WHEREAS

KINETIC CONCEPTS INC., 8023 Vantage Drive, San Antonio, Texas 78230, United States of America

(hereinafter together with his or their successors and assigns or any of them called "the patentee") is entitled to be registered as the proprietor of the patent hereinafter granted:

Address for service: BALDWIN SHELSTON WATERS, Level 14, NCR House, 342 Lambton Quay, Wellington, New Zealand

NOW, THEREFORE, We by these letters patent give and grant to the patentee our special licence, full power, sole privilege, and authority, that the patentee by himself, his agents, or licensees and no others, may subject to the provisions of any statute or regulation for the time being in force make, use, exercise and vend the said invention within New Zealand and its dependencies during a term of twenty years from 31 March 2000 and that the patentee shall have and enjoy the whole profit and advantage from time to time accruing by reason of the said invention during the said term:

AND WE strictly command all our subjects whomsoever within New Zealand and its dependencies that they do not at any time during said term either directly or indirectly make use of or put into practice the said invention, nor in any way imitate the said invention without the consent, licence, or agreement of the patentee in writing under his hand, on pain of incurring such penalties as are prescribed by law and of being answerable to the patentee according to law for his damages thereby occasioned:

PROVIDED ALWAYS:

(1) That these letters patent shall determine and become void if the patentee does not from time to time pay the renewal fees prescribed by law in respect of the patent:

(2) That these letters patent are revocable on any of the grounds prescribed by the Patents Act 1953 as grounds for revoking letters patent:

(3) That nothing in these letters patent shall prevent the granting of licences in the manner in which and for the considerations on which they may by law be granted:

(4) That these letters patent shall be construed in the most beneficial sense for the advantage of the patentee.

IN WITNESS whereof We have caused these letters patent to be signed and sealed on 9 March 2004 with effect from 31 March 2000.

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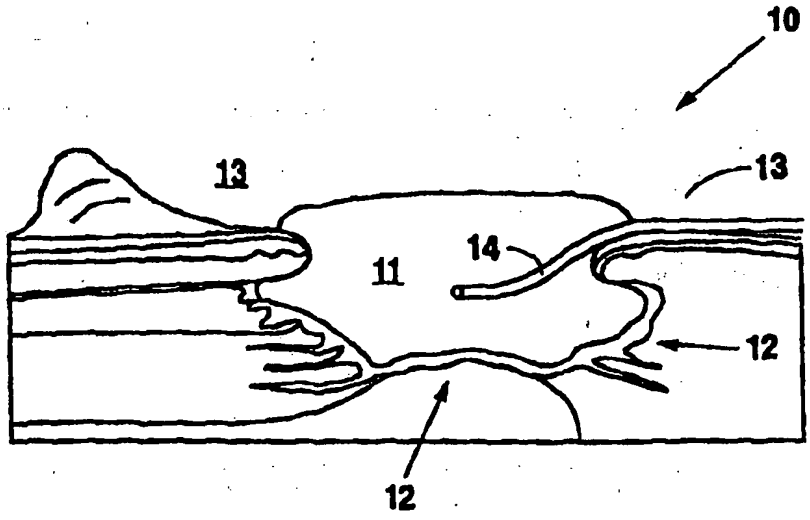

(57) Abstract

A method, and apparatus for the introduction to a wound under vacuum assisted closure (VAC) therapy of a wound healing agent, generally comprises a foam pad (11) for insertion substantially into a wound site (12), and a wound drape (13) for sealing enclosure of the foam pad at the wound site. The foam pad is placed in fluid communication with a vacuum source for promotion of fluid drainage. Additionally, the foam pad is predisposed, through grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), anti-microbial or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

VACUUM ASSISTED CLOSURE SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT

TECHNICAL FIELD:

The present invention relates to the healing of wounds. More specifically, the present invention relates to the vacuum assisted closure (VAC) of wounds wherein a growth factor or other agent is introduced to a wound site through grafting with a VAC pad in order to facilitate wound healing.

BACKGROUND ART:

The following discussion of the prior art is intended to present the invention in an appropriate technical context and allow its significance to be properly appreciated. Unless clearly indicated to the contrary, however, reference to any prior art in this specification should not be construed as an admission that such art is widely known or forms part of common general knowledge in the field.

Wound closure involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until recently, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the

insertion points, which can eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not repairable by suturing or stapling generally require prolonged hospitalisation, with its attendant high cost, and major surgical procedures such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic ostemoyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative pressure, commonly referred to as vacuum assisted closure (VAC) therapy, typically involves mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, VAC therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While VAC therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the inflammatory process is very unique to the individual patient, even the addition of VAC therapy does not result in a fast enough response, especially during the occlusion and initial cleanup and rebuilding stages, for adequate healing of some wounds.

It is an object of the invention to overcome or ameliorate one or more of the deficiencies of the prior art, or at least to provide a useful alternative.

DISCLOSURE OF THE INVENTION:

According to the invention there is provided a therapeutic combination for promoting wound healing in mammals, said therapeutic combination comprising:

a porous pad which is permeable to fluids and adapted for positioning within a sealable space defined in part by a wound surface;

a tube having a first end in fluid communication with said porous pad and a second end in fluid communication with a vacuum source, said vacuum source being adapted to apply negative pressure to said porous pad through said tube; and

said porous pad being predisposed with a wound healing factor.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

BRIEF DESCRIPTION OF THE DRAWINGS:

A preferred embodiment of the invention will now be described with reference to Figure 1, which shows a partially cut away perspective view of a preferred embodiment of the present invention as applied to a mammalian wound site.

PREFERRED EMBODIMENT OF THE INVENTION:

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention – a vacuum assisted closure system with provision for introduction of agent, the scope of which is limited only by the claims appended hereto.

Referring now to the figure, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into a wound site 12 and a wound drape 13 for sealing enclosure of the foam pad 11 at the wound site 12. According to the invention, the

foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage. Additionally, the foam pad 11 is predisposed, through grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), anti-microbials or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

According to the preferred embodiment of the present invention, the foam pad 11, wound drape 13 and vacuum source are implemented as known in the prior art, each of which is detailed in U.S. patent application Serial No. 08/517,901 filed August 22, 1995. By this reference, the full disclosure of U.S. patent application Serial No. 08/517,901 ("the '901 application"), including the claims and the drawings, is incorporated herein as though now set forth in its entirety. Additionally, such a VAC system is readily commercially available through Kinetic Concepts, Inc. of San Antonio, Texas, U.S.A. and/or its subsidiary companies.

As detailed in the '901 application, the foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction, but in this application may comprise a conventional sponge cellulose type dressing as necessary for introduction of the desired agent. As also detailed in the '901 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 14, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump. Finally, the '901 application also details the wound drape 13, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '901 application are generally employed as known in the art with the exception that the foam pad 11 of the present invention is modified as necessary for the introduction of a growth factor. Such growth factors as the basic fibroblast growth factor (bFGF) are known to accelerate wound healing due to their potent angiogenesis and granulation tissue formation activities. As has been demonstrated even with difficult to heal wounds, such as infected wounds, burn wounds and diabetic wounds, the resultant activities lead to the rapid reepitherialization and contraction of the wound. The combination of VAC therapy with growth factor introduction, through the modification of the foam pad 11 and predisposition thereof with the bFGF, is therefore thought to be an important contribution to the wound healing arts. Likewise, the present method presents an excellent opportunity for

the introduction to the wound site 12 of anti-microbial agents, whether alone or in combination with bFGF or other agents.

It will be appreciated that the illustrated therapeutic combination provides an improvement to known VAC therapy modalities through the introduction of growth factors and other agents that facilitate wound healing.

While the foregoing description is exemplary of the preferred embodiment of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description, the accompanying drawings and the claims drawn hereto. For example, those of ordinary skill in the art will recognize that while the preferred embodiment of the present invention comprises grafting the desired agent onto the foam pad 11 of the VAC system, those of ordinary skill in the art, with the benefit of this exemplary disclosure, will readily recognize many substantially equivalent modes for introduction of the desired agent. For example, in the case of a foam pad 11 that has not been predisposed with an agent or that has been predisposed with an agent which, over time, has subsequently been exhausted into the wound site 12, the desired agent may be injected with a needle and syringe, or the like, through the wound drape 13 and into the foam pad 11. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the present invention, which is limited only by the claims appended hereto.

Although the invention has been described with reference to a specific example, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

CLAIMS:

What is claimed is:

1. A therapeutic combination for promoting wound healing in mammals, said therapeutic combination comprising:

a porous pad which is permeable to fluids and adapted for positioning within a sealable space defined in part by a wound surface;

a tube having a first end in fluid communication with said porous pad and a second end in fluid communication with a vacuum source, said vacuum source being adapted to apply negative pressure to said porous pad through said tube; and

said porous pad being predisposed with a wound healing factor.

2. The therapeutic combination as recited in claim 1, wherein said wound healing factor comprises basic fibroblast growth factor.

3. The therapeutic combination as recited in claim 2, wherein said basic fibroblast growth factor is grafted to said porous pad.

4. The therapeutic combination as recited in claim 1, wherein said wound healing factor comprises an anti-microbial agent.

5. The therapeutic combination as recited in claim 4, wherein said anti-microbial agent comprises an antibiotic.

6. The therapeutic combination as recited in any of the preceding claims, wherein said porous pad is predisposed with a plurality of wound healing factors.

7. The therapeutic combination as recited in any of the preceding claims, said therapeutic combination further comprising a wound drape for sealing said porous pad within said sealable space.

8. The therapeutic combination as recited in claim 7, wherein a quantity of a wound healing factor is introduced to said porous pad by injection through said wound drape.

9. The therapeutic combination as recited in claim 8, wherein said quantity of wound healing factor is in addition to said wound healing factor predisposed upon said porous pad.

10. The therapeutic combination as recited in claim 9, wherein said quantity of wound healing factor comprises the same type of factor as said wound healing factor predisposed upon said porous pad.

11. A therapeutic combination substantially as herein described with reference to any one of the embodiments of the invention shown in the accompanying drawings.

DATED this 4th day of June, 2002
KINETIC CONCEPTS, INC.

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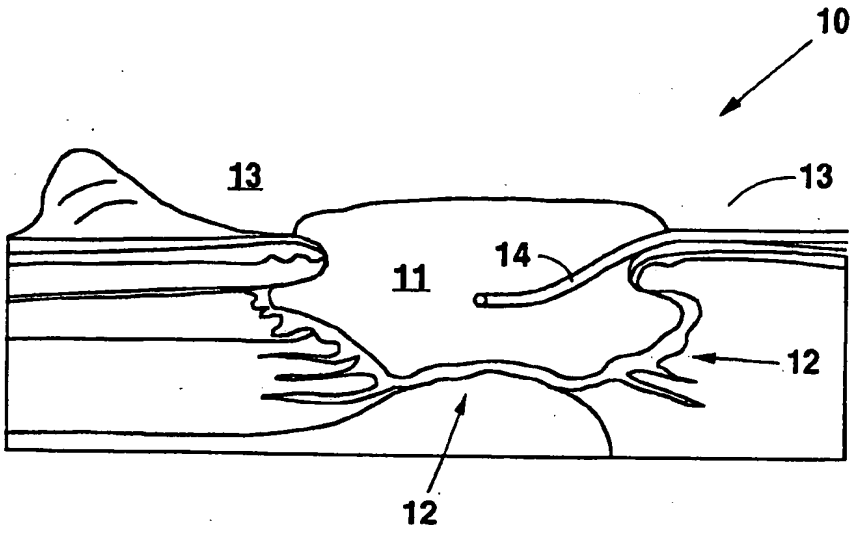

Fig. 1